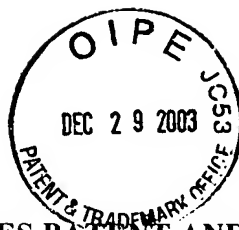


IBIS0060-100/DIBIS0044US



JFW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: David J. Ecker, et al

Serial No.: 10/728,486

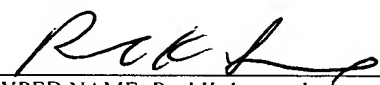
Group Art Unit: Not Yet Assigned

Filing Date: December 5, 2003

Examiner: Not Yet Assigned

For: **METHODS FOR RAPID IDENTIFICATION
OF PATHOGENS IN HUMANS
AND ANIMALS**

DATE OF DEPOSIT: 22 DECEMBER 2003
I HEREBY CERTIFY THAT THIS PAPER IS BEING
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ALEXANDRIA, VA 22313-1450


TYPED NAME: Paul K. Legaard
REGISTRATION NO: 38,534

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☒ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☐ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☒ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references (BA-BG, CA-CN, S1-S44) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed.

EXCEPT THAT:

- ☐ In view of the voluminous nature of references @@, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

- ☐ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. _____ filed on _____.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Petition

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$_____. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

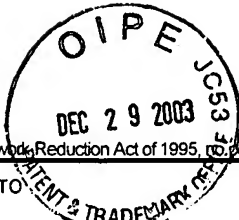
Respectfully submitted,



Paul K. Legaard
Registration No. 38,534

Dated: 22 November 2003

COZEN O'CONNOR, P.C.
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(215) 701-2013 - Facsimile



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 8

Complete if Known

Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AA	US-5,484,908	01/16/1996	Froehler et al	
	AB	US- 5,502,177	03/26/1996	Matteucci et al	
	AC	US- 5,547,835	08/20/1996	Koster	
	AD	US- 5,605,798	02/25/1997	Koster	
	AE	US- 5,622,824	04/22/1997	Koster	
	AF	US- 5,645,985	07/08/1997	Froehler et al	
	AG	US- 5,691,141	11/25/1997	Koster	
	AH	US- 5,763,588	07/09/1998	Matteucci et al	
	AI	US- 5,830,653	11/03/1998	Froehler et al	
	AJ	US- 5,849,492	12/15/1998	Rogan	
	AK	US- 5,872,003	02/16/1999	Koster	
	AL	US- 5,965,363	10/12/1999	Monforte et al	
	AM	US- 6,005,096	12/21/1999	Matteucci et al	
	AN	US- 6,007,992	12/28/1991	Lin et al	
	AO	US- 6,028,183	02/22/2000	Lin et al	
		US-			
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		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	BA	WO97/33000	09/12/97			
	BB	WO97/37041	10/09/97			
	BC	WO98/12355	03/26/98			
	BD	WO98/54751	12/03/98			
	BE	WO99/14375	03/25/99			
	BF	WO99/31278	06/24/99			
	BG	WO98/20166	05/14/98			

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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B(10-01)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/728,486
		Filing Date	December 5, 2003
		First Named Inventor	David J. Ecker
		Group Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
Sheet 2 of 8	Attorney Docket Number	IBIS0060-100/DIBIS0044US	

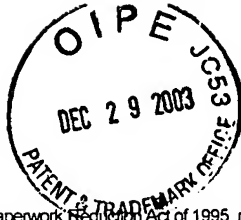
OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Aaserud, D.J., et al., "Accurate base composition of double-strand DNA by mass spectrometry," J. Am. Soc. Mass Spec., 1996, 7, 1266-1269	
	CB	Bowen, J.E., et al., "The native virulence plasmid combination affects the segregational stability of a theta-replicating shuttle vector in bacillus anthracis var, New Hampshire," J. Appl. Microbiol., 1999, 87, 270-278	
	CC	Hurst, G.B., et al., "Detection of bacterial DNA polymerase chain reaction products by matrix-assisted laser desorption/ionization mass spectrometry," Rapid Commun. Mass Spec., 1996, 10, 377-382	
	CD	Loakes, D., et al., "Nitroindoles as universal bases," Nucleosides and Nucleotides, 1995, 14(3-5), 1001-1003	
	CE	Muddiman, D.C., et al., "Precise mass measurement of a double-stranded 500 base-pair (309 kDa) polymerase chain reaction product by negative ion electrospray ionization fourier transform ion cyclotron resonance mass spectrometry," Rapid Commun. Mass Spec., 1999, 13, 1201-1204	
	CF	Muddiman, D.C., et al., "Length and base composition of PCR-amplified nucleic acids using mass measurements from electrospray ionization mass spectrometry," Anal. Chem., 1997, 69, 1543-1549	
	CG	Sala, M., et al., "Ambiguous base pairing of the purine analogue 1-(2-deoxy-β-D -ribofuranosyl)-imidazole-4-carboxamide during PCR," Nucl. Acids Res., 1996, 24(17), 3302-3306	
	CH	Van Aerschot, A., et al., "In search of acyclic analogues as universal nucleosides in degenerate probes," Nucleosides and Nucleotides, 1995, 14(3-5), 1053-1056	
	CI	Wunschel, D.S., et al., "Heterogeneity in bacillus cereus PCR products detected by ESI-FTICR mass spectrometry," Anal. Chem., 1998, 70, 1203-1207	
	CJ	Mushegian, A.R., et al., "A minimal gene set for cellular life derived by comparison of complete bacterial genomes," Proc. Natl. Acad. Sci. USA, 1996, 93, 10268-10273	
	CK	Welham, et al., Rapid Communications in Mass Spectroscopy (1988) 12:176-180	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 8

Complete if Known

Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

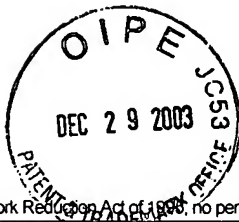
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CL	Cho et al., "Application of the ribonuclease P (RNaseP) RNA gene sequence for phylogenetic analysis of the genus Saccharomonospora," Int'l. J. Systematic Biol. (1998) 48:1223-1230	
	CM	Matray, et al., "Synthesis and properties of RNA analogs - oligoribonucleotide N3'->P5' phosphoramidates," Nucleic Acids Res. (1999) 3976-3985	
	CN	Li, et al., "Single nucleotide polymorphism determination using primer extension and time of flight mass spectrometry," Electrophoresis (1999) 20:1258-1265	

Examiner
SignatureDate
Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 4 of 8

Complete if Known

Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

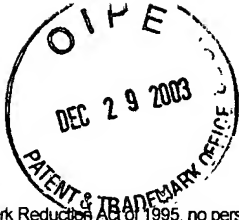
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	S1	BAKER, et al., "Review and re-analysis of domain-specific 16S primers," J. Microbiol. Methods (2003) 55:541-555.	
	S2	BENSON, et al., "Advantages of Thermococcus kodakaraensis (KOD) DNA polymerase for PCR-mass spectrometry based analyses," J. Am. Soc. Mass Spectrom. (2003) 14:601-604.	
	S3	BLACK, et al., "Detection of trace levels of tricothecene mycotoxins in human urine by gas chromatography-mass spectrometry," J. Chromatog. (1986) 367:103-115.	
	S4	CAMPBELL and HUANG, "Detection of California serogroup Bunyavirus in tissue culture and mosquito pools by PCR," J. Virol. Methods (1996) 57:175-179.	
	S5	CHEN, et al., "A universal PCR primer to detect members of the Potyviridae and its use to examine the taxonomic status of several members of the family," Arch. Virol. (2001) 146:757-766.	
	S6	CONRAD, et al., "16S-23S rDNA internal transcribed spacer sequences for analysis of the phylogenetic relationships among species of the genus Fusobacterium," Intl. J. System. Evol. Microbiol. (2002) 52:493-499.	
	S7	DASEN, et al., "Classification and identification of Propionibacteria based on ribosomal RNA genes and PCR," System. Appl. Microbiol. (1998) 21:251-259.	
	S8	DEFORCE, et al., "Characterization of DNA oligonucleotides by coupling of capillary zone electrophoresis to electrospray ionization Q-TOF mass spectrometry," Anal. Chem. (1998) 70:3060-3068.	
	S9	DEMASURE, et al., "A set of universal primers for amplification of polymorphic non-coding regions of mitochondrial and chloroplast DNA in plants," Mol. Ecol. (1995) 4:129-131.	
	S10	FLORA, et al., "Dual-micro-ESI source for precise mass determination on a quadrupole time-of-flight mass spectrometer for genomic and proteomic applications," Anal. Bioanal. Chem. (2002) 373:538-546.	
	S11	FOX, et al., "Identification of Brucella by ribosomal-spacer-region PCR and differentiation of Brucella canis from other Brucella spp. pathogenic for humans by carbohydrate profiles," J. Clin. Microbiol. (1998) 36:3217-3222.	

Examiner
SignatureDate
Considered

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 5 of 8

Complete if Known

Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

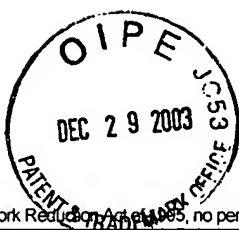
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	S12	FOX et al., "Report of the 'Bioterrorism Workshop'", J. Microbiol. Methods (2002) 51:247-254.	
	S13	GRIFFEY and GREIG, "Detection of base pair mismatches in duplex DNA and RNA oligonucleotides using electrospray mass spectrometry," SPIE (1997) 2985:82-86.	
	S14	GRIFFIN, et al., "Direct genetic analysis by matrix-assisted laser desorption/ionization mass spectrometry," proc. Natl. Acad. Sci. USA (1999) 96:6301-6306.	
	S15	HANNIS and MUDDIMAN, "Accurate characterization of the tyrosine hydroxylase forensic allele 9.3 through development of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (1999) 13:954-962.	
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	S17	HANNIS and MUDDIMAN, "Detection of double-stranded PCR amplicons at the attomole level electrosprayed from low nanomolar solutions using FT-ICR mass spectrometry," Fresenius J. Anal. Chem. (2001) 369:246-251.	
	S18	HAYASHI, et al., "Phylogenetic analysis of the human gut microbiota using 16S rDNA clone libraries and strictly anaerobic culture based methods," Microbiol. Immunol. (2002) 46:535-548.	
	S19	HOFFMANN, et al., "Universal primer set for the full-length amplification of all influenza A viruses," Arch. Virol. (2001) 146:2275-2289.	
	S20	ISOLA, et al., "MALDI-TOF mass spectrometric method for detection of hybridized DNA oligomers," Anal. Chem. (2001) 73:2126-2131.	
	S21	JANKOWSKI and SOLER, "Mass spectrometry of DNA: Part 2* Quantitative estimation of base composition," Eur. J. Mass Spectrom. Biochem. Med. Environ. Res. (1980) 1:45-52.	
	S22	KAGEYAMA and BENNO, "Rapid detection of human fecal Eubacterium species and related genera by tested PCR method," Microbiol. Immunol. (2001) 45:315-318.	

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Considered

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 6 of 8

Complete if Known

Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	S23	LITTLE, et al., "Rapid sequencing of oligonucleotides by high-resolution mass spectrometry," J. Am. Chem. Soc. (1994) 116:4893-4897.	
	S24	LIU, et al., "Improving the microdialysis procedure for electrospray ionization mass spectrometry of biological samples," J. Mass Spectrom. (1997) 32:425-431.	
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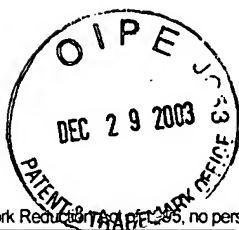
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Sheet 7 of 8

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Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

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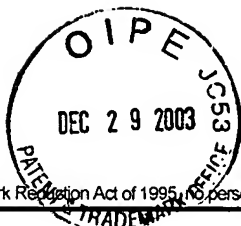
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Sheet 8 of 8

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Application Number	10/728,486
Filing Date	December 5, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0060-100/DIBIS0044US

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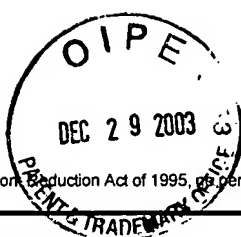
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	S44	WUNSCHER, et al., "Mass spectrometric characterization of DNA for molecular biological applications: advances using MALDI and ESI," Adv. Mass Spectrom., Vol. 14, Karjalainen, et al., (eds.) 1998, Elsevier, Amsterdam.	

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	Filing Date	December 5, 2003	
	First Named Inventor	David J. Ecker	
	Art Unit	Not Yet Assigned	
	Examiner Name	Not Yet Assigned	
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